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Innovation in medical technology spans a range of activities—from basic and applied research efforts in areas including bioinstrumentation, artificial organs, and cellular bioprocessing, to developmental efforts that yield products, such as diagnostic imaging equipment and implantable devices.  

It is a dynamic, continuous, and interactive process, rarely proceeding in a linear or predictable manner. Medical device innovation is characterized more often by small, incremental steps than by bold, technological bounds. The direction of the process is sensitive to a variety of forces, including the availability of funds, the reactions of users and regulators, and more general market trends.

The innovation process engages many participants, including the National Institutes of Health (NIH) and other federal agencies, universities and research laboratories, and private-sector medical technology companies, both large and small. Large companies tend to focus more on incremental improvements during the growth or mature stages of innovation; smaller companies are noted for their innovative zest during the early stages of device development, although there are many notable exceptions to this rule. Further, small firms often do not possess the resources or expertise to manage the uncertainty and resistance often associated with innovation.

Investment In Research And Development

Public sector. Federally funded universities and medical centers support
a variety of research and development (R&D) activities, although private industry is the dominant supporter of development and commercialization. According to a recent study conducted by the Congressional Research Service, the federal government invested approximately $422 million in medical device R&D in fiscal year 1992, down $27 million from the year before (Exhibit 1).\(^4\) By way of comparison, medical device funding is approximately one-quarter of that for pharmacology R&D at selected federal agencies ($1.83 billion in N 1992).

The majority of federal funding of medical device R&D is supported by NIH. Specifically, NIH funding of intramural and extramural programs (including support for small-business innovation research projects) was larger than that for all other agencies combined. In contrast, however, is the small proportion of NIH's total budget directed toward medical device R&D. In FY 1992 NIH medical device R&D spending ($354 million) accounted for less than 5 percent of the total NIH budget of $8.3 billion for the year.\(^5\)

**Private sector.** The medical technology industry maintains an intensive commitment to R&D. In 1992 the industry invested 6.7 percent of its sales in R&D, representing an increase of more than 6 percent over the previous year (Exhibit 2). Overall, industry invested only 3.7 percent of its sales in R&D. R&D investment in the medical technology industry exceeded that for several other high-technology industries as well, including aerospace (4.4 percent) and the electrical and electronics industry (6 percent).\(^6\)

There is significant variation in R&D spending across and within medical technology industry sectors (Exhibit 3). For example, within the *in vitro*
and in vivo diagnostic sector in 1991, 75 percent of companies spent 10 percent of sales or more for R&D, and 25 percent of companies spent 126.7 percent of sales or more for R&D.

**Exhibit 2**  
Research And Development Of Medical Device Industry, As A Percentage Of Sales, 1988-1992

<table>
<thead>
<tr>
<th>Percent</th>
<th>All industry average</th>
<th>Health care medical products and services</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>3.4</td>
<td>6.2</td>
</tr>
<tr>
<td>4</td>
<td>3.4</td>
<td>6.2</td>
</tr>
<tr>
<td>2</td>
<td>3.4</td>
<td>6.2</td>
</tr>
<tr>
<td>0</td>
<td>3.4</td>
<td>6.2</td>
</tr>
</tbody>
</table>


**Exhibit 3**  
Variations In R&D Spending As A Percentage Of Sales, By Sector, Medical Technology Industry, 1991

<table>
<thead>
<tr>
<th>R&amp;D/sales distribution</th>
<th>In vitro and in vivo diagnostic instruments and supplies</th>
<th>Surgical, prosthetic, and surgical equipment and supplies</th>
<th>Orthopedic, prosthetic, and surgical equipment and supplies</th>
<th>X-ray apparatus and tubes and related irradiation apparatus</th>
<th>Electromedical and electrotherapeutic apparatus</th>
<th>Ophthalmic distribution substances and supplies</th>
</tr>
</thead>
<tbody>
<tr>
<td>75% of companies have R&amp;D costs greater than or equal to</td>
<td>10.0%</td>
<td>2.6%</td>
<td>1.4%</td>
<td>2.0%</td>
<td>4.0%</td>
<td>6.8%</td>
</tr>
<tr>
<td>50% of companies have R&amp;D costs greater than or equal to</td>
<td>29.9</td>
<td>5.3</td>
<td>3.2</td>
<td>4.1</td>
<td>10.2</td>
<td>10.1</td>
</tr>
<tr>
<td>25% of companies have R&amp;D costs greater than or equal to</td>
<td>126.7</td>
<td>8.0</td>
<td>5.7</td>
<td>28.0</td>
<td>19.5</td>
<td>23.4</td>
</tr>
</tbody>
</table>

Sources: Health Care Technology Institute, “Variations in Research and Development Spending within the Medical Technology Industry,” Insight (June 1993); and data from Price Waterhouse based on calculations from Compustat (286 total observations).
percent or more of sales for R&D. Moreover, when compared across sectors, the in vitro and in vivo diagnostic R&D spending ratio was significantly higher than that for orthopedic, prosthetic, and surgical appliances and supplies.

Venture capital funding historically has been critical to the R&D efforts of smaller start-up companies. Because such companies make up nearly three-quarters of the health care technology industry and in many cases are the most innovative, availability of venture capital financing is a critical element for continued medical device innovation. The level of venture capital funding for the medical technology industry increased from approximately $300 million in 1988 to about $426 million in 1992, an increase of 42 percent. This increase in industry funding occurred at a time when overall venture capital funding declined from a high of $7.7 billion in 1988 to $5.6 billion in 1992. As a result of these contrasting trends, medical device venture capital funding as a percentage of total venture capital funding increased from 3.9 percent in 1988 to 7.6 percent in 1992.

An interesting trend occurred during this period in terms of the distribution of funding among companies. While aggregate venture capital funding for the industry increased substantially from 1988 to 1992, the number of medical technology companies receiving the funding remained stable. As a result, venture capital investment per company rose from an average of $2.4 million in 1988 to $3.2 million in 1992.

These data, combined with anecdotal reports from companies and investors, suggest that as selection criteria have narrowed (in part because of increased regulatory risks), a smaller number of companies are receiving venture capital financing. Moreover, investors are moving away from “seed” capital (first-round financing for concept or product development) toward later financing rounds. Companies at a later stage of product development carry less risk and therefore greater investment potential, according to many investors.

Finally, venture capital investors speculate that funding for medical technology companies may not continue at current levels. Investors point to uncertainty about health care reform, changes in the Food and Drug Administration’s (FDA’s) medical device clearance process, and changes in the market valuation of public medical device companies as factors that will affect future funding. These trends, in fact, are reflected in more recent data. Venture capital funding of medical device firms declined 34 percent in 1993, to a total of $283 million.

Patents

Patent protection is relatively less important for medical devices than it
is for pharmaceutical or biotechnology products. Device innovation often occurs over an abbreviated time period, and technological obsolescence can occur in a matter of months, rather than years. Nonetheless, trends in medical device patent data can reveal useful longitudinal information on technological activity, including breakthrough developments as well as innovation at its earlier stages.

Since 1980 medical devices have been patented in the United States at an increasing rate, reaching a total of 4,871 patents granted in 1993 (Exhibit 4). U.S. corporations, government, and individuals dominate ownership of these patents, although the proportion of U.S. ownership declined during 1980-1990. More recently, however, the proportion of patents granted to U.S. entities has increased to 75 percent—the highest level for the period.

A close examination of patents granted during 1969-1993 reveals the many sources of innovative activity for medical devices. During this period more than 600 organizations were granted ten or more patents; these included universities, private citizens, federal government agencies, and medical device companies.

Product Regulatory Clearance

One indicator of device innovation output is the number of products regulated by the FDA. However, regulatory clearance data need to be examined with caution, because these data are subject to changes in FDA policy and other factors that have less to do with the level of innovation activity itself.

Exhibit 4
U.S. Medical Device Patents Granted, By Ownership, 1980-1993

<table>
<thead>
<tr>
<th>Number of patents</th>
<th>U.S. owned</th>
<th>Foreign owned</th>
</tr>
</thead>
<tbody>
<tr>
<td>5,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---|---|---|---
2,070 | 2,532 | 70% | 25%
2,070 | 2,532 | 70% | 25%
2,070 | 2,532 | 70% | 25%
2,070 | 2,532 | 70% | 25%

The FDA classifies a medical technology product based on the degree of potential risk it poses to humans. Class I products pose the least risk; Class II products pose moderate risk; and Class III products pose the most significant risk and are subject to the most stringent controls. For most products the FDA must conduct a premarket review prior to market introduction. Depending on the individual device, clearance can be obtained through a premarket notification [510(k)], or a premarket approval (PMA). Products cleared through a 510(k) are, by definition, “substantially equivalent” to an earlier, legally marketed device. These products tend to reflect incremental innovations—a common characteristic of device development. Products approved through a PMA represent greater potential risk to patients and are not substantially equivalent to an earlier device. As such, these products tend to represent new, often breakthrough technologies.

During the period FY 1988–FY 1993, the number of PMA requests received by the FDA declined, with submissions falling from a high of ninety-six in FY 1988 to a low of forty in FY 1993 (Exhibit 5). During the same period the number of PMA submissions approved each fiscal year also declined, with the exception of FY 1993. This trend may be due to increased scrutiny in FDA product reviews in recent years, which has affected both the rate and the timeliness of approvals for PMA submissions. Increasingly, the FDA has required additional data on products prior to approval. These data must be acquired over a longer period of time and at additional expense, thereby delaying PMA submissions to the agency. Moreover, some firms may, in the face of increased FDA scrutiny, decide to abandon a new product because they assess the financial risk as too great to justify moving forward with development.

On the other hand, the number of 510(k) submissions has generally increased in recent years, although there has been significant variation

<table>
<thead>
<tr>
<th>Exhibit 5</th>
<th>FDA Original Premarket Approval (PMA) Applications And Premarket Notifications [510(k)s], Fiscal Years 1988-1993</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PMAs</strong></td>
<td></td>
</tr>
<tr>
<td>Number approved</td>
<td>46</td>
</tr>
<tr>
<td><strong>510(k)s</strong></td>
<td></td>
</tr>
<tr>
<td>Number received</td>
<td>5,536</td>
</tr>
<tr>
<td>Number substantially equivalent</td>
<td>4,432</td>
</tr>
</tbody>
</table>


a PMAs approved in a given year were most likely received in a prior year. Further, the number of approvals will be lower than the number of receipts, because of withdrawal of applications and other circumstances.
from year to year. The number of 510(k) submissions increased from 5,536 in N 1988 to 6,288 in FY 1993; the greatest number of submissions (7,022) occurred in N 1989. This trend may be due to the fact that firms are continuing to pursue incremental improvements to products. Here again, however, increased FDA scrutiny and additional data requirements have affected the number of submissions found to be substantially equivalent. While the number of submissions increased from FY 1988 to FY 1993, the number of substantially equivalent decisions, on average, declined by 1.6 percent per year. Moreover, the total review time for 510(k)s increased more than 60 percent for the period FY 1988 to FY 1992. According to a recent report by the U.S. General Accounting Office, the total review time in FY 1993 increased 55 percent over the previous year.

Another interesting aspect of product clearance lies in the composition of the companies submitting device applications. According to the FDA, in N 1991, 53 percent of the seventy-five PMAs submitted were submitted by small firms with fewer than 500 employees, and 47 percent were submitted by larger firms with 500 or more employees (Exhibit 6). The composition of companies submitting PMAs is not in proportion with the overall makeup of the industry. According to the FDA, 98 percent of establishments in the medical device and radiological health industry have fewer than 500 employees, yet these smaller companies accounted for only 53 percent of PMA submissions. In contrast, 2 percent of the industry is made

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**Exhibit 6**

A Comparison Of Size Distribution Of Companies Submitting PMAs With Overall Industry Distribution

![Chart showing size distribution of companies submitting PMAs compared to overall industry distribution](chart.png)

**Source:** FDA Center for Devices and Radiological Health, Division of Planning, Evaluation, and Information Services, Evaluation Branch, unpublished data.

a PMAs are premarket approvals.

b Establishment size of medical device and radiological health industry based on 1987 census data from U.S. Department of Commerce.
up of companies with 500 or more employees, yet these companies provided 47 percent of all PMA submissions in FY 1991. This trend is not surprising when one considers the role of small and large companies in the innovation process. While smaller companies are generally more innovative, larger companies often have the resources to bring new product innovations through the regulatory process and to market.

**Market Acceptance**

Perhaps the ultimate indicator of product innovation lies in the ability to retain and expand world markets. In 1993 nearly 24 percent of production of the U.S. health care technology industry was exported to other countries. For several years the U.S. medical technology industry has dominated the world market, capturing approximately one-half of total world production in 1993. The closest global competitor is the European Union, supplying 27 percent of global production of technology; Japan ranks third with about 18 percent of production.\(^{16}\)

Of the total U.S. medical technology industry production of $41.7 billion in 1993, $9.8 billion was exported. U.S. exports rose at an average annual rate of 16.3 percent for the period 1988 to 1993, while imports increased at a slower rate of 11.5 percent per year during the same period, reaching $5.1 billion in 1993.\(^{17}\) Domestic consumption of medical technology products totaled $37.1 billion in 1993, an increase of 7.3 percent from the previous year and slightly behind the average annual consumption growth of 8 percent per year from 1988 to 1993.

Strong growth of medical technology markets, both domestically and abroad, has consistently placed several sectors of the industry among the fastest growing in the United States. According to the Department of Commerce, four of the top ten fastest-growing sectors of U.S. manufacturing industries from 1988 to 1993 were involved in the manufacture of health care technology.\(^{18}\)

**Prospects For The Future**

U.S. investment in medical technology R&D has yielded significant advances in patient care and has spawned an industry that contributes positively to the domestic economy, as well as being highly competitive in global markets. Yet, based on selected indicators, a shift in innovative activity may be on the horizon, in terms of both the nature of and the key investors in this process.

Recently, federal support for medical technology R&D has shown signs of declining. The public sector is uniquely positioned to fund much of the
basic and applied research that leads to new and innovative advances in medical technology. Sustained reductions in the funding of this important aspect of innovation could, over the years, affect the pipeline for new medical products. While private-sector R&D investment has increased in recent years, this may not sufficiently offset declining public-sector funding; the private sector tends to invest more heavily in developmental research, rather than in the basic and applied disciplines. Also troubling are indications from venture capital investors that they are shifting away from funding small start-up companies—often the most innovative. To the extent that PMA applications represent new product innovations, clearly fewer of these innovations have been introduced in the market in recent years. On the other hand, private-sector innovation activities continue to contribute significantly to incremental improvements, as measured by 510(k) submissions to the FDA in recent years.

These trends need to be considered in a broader context, however. Shifts in the marketplace, characterized by new and emerging structures and purchasing incentives, could in many respects send the strongest signals to innovators of new medical products. Increased price-sensitivity, greater product standardization, heightened product liability concerns, and changing relationships among providers, purchasers, and suppliers could bring about significant and long-lasting changes in innovation activity for medical technology.

The consequences of these developments will not be experienced for many years. But for policymakers, vigilance is critical. For while the innovation process often occurs slowly and with little fanfare, the results can be dramatic and enduring.

The author thanks Maria N. Briones for assistance with the preparation of this manuscript.

NOTES

1. For purposes of this DataWatch, medical technology refers to medical devices, diagnostics, and, where noted, health care information systems. This includes the following industrial sectors, based on the Standard Industrial Classification (SIC) Manual of the U.S. Department of Commerce: surgical and medical instruments and apparatus (SIC 3841); orthopedic, prosthetic, and surgical appliances and supplies (SIC 3842); dental equipment and supplies (SIC 3843); x-ray apparatus and tubes (SIC 3844); electro-medical and electrotherapeutic apparatus (SIC 3845); and in vitro and in vivo diagnostic substances (SIC 2835).

2. Small medical device firms (those with fewer than fifty employees) constitute approximately 75 percent of companies in the industry, based on 1992 data from the FDA Office of Device Registration and Listing and the Division of Small Manufacturers Assistance.

3. Leighton Read and Kenneth Lee Jr. address this issue in greater detail. J.L. Read and
K.B. Lee Jr., “Health Care Innovation: Progress Report and Focus on Biotechnology,”
Device-Related Research and Development” (27 April 1994).
5. Ibid.
8. Ibid.
9. Based on data and analysis from Venture Economics, a division of Securities Data
Company, Inc.
Office defines medical devices as including the following: methods and apparatus
for the inspection and treatment of abnormal conditions (for example, diseases,
wounds, and so forth) in humans and animals; methods, apparatus, implements, or
devices for the treatment of teeth or gums, and for the replacement of teeth; artificial
substitutes or parts for a human body (prosthesis) including specialized elements,
accessories, and operating and control devices therefore; eye examining and testing
equipment (spectacles and eyeglasses are not included in this profile); computer systems
as they relate to the life sciences and to medical applications; and chemistry as it relates
to analytical and immunological testing for a named disease, body condition, or organ
function.
11. Food and Drug Administration, Office of Device Evaluation, Annual Report, Fiscal Year
12. Ibid.
13. The dramatic rise in 510(k) submissions in FY 1989 was due to the FDA’s response to
the acquired immunodeficiency syndrome (AIDS) crisis—the agency withdrew exempted surgical and patient gloves from the 510(k) process. As a result, the FDA received over 1,500 510(k)s for gloves during the fiscal year.
U.S. GPO, 2 February 1994).
17. Ibid.
18. Four of the top ten fastest-growing sectors of U.S. manufacturing industries are in the
production of health care technology: SICs 3844 (first), 3845 (second), 3844 (third),
(December 1993).